



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

SEP 22 2006

Mr. Egon A. Landgraf  
Agent  
GUNA, Inc.  
4416 Glenwood Hills Drive NE  
Albuquerque, New Mexico 87111

Dear Mr. Landgraf:

This is in response to your letter of September 13, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that GUNA, Inc. is making the following claims for the product **GUNA-NONI**:

“[H]elps from seasonal illness.”

“Helps recovery from seasonal illness, provides support to the respiratory tract during the cold season and for smoking related troubles.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases such as the common cold and those caused by smoking. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

97S 0163 LET 903

Page 2 - Mr. Egon A. Landgraf

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Vasilios Frankos", with a stylized flourish at the end.

Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

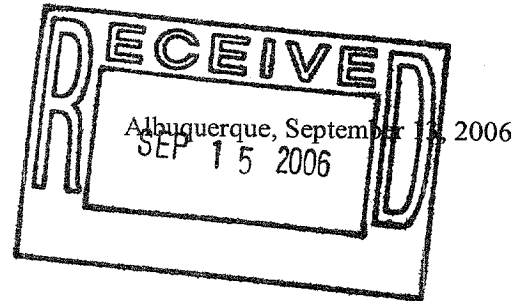
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Denver District Office, Office of Compliance, HFR-SW240



Certified MAIL Return Receipt Requested

Office of Nutrition Products  
Labelling and Dietary Supplements  
FOOD & DRUG ADMINISTRATION  
5100 Paint Branch Parkway  
College Park, Maryland 20740-3835



**Ref: Notification pursuant to 21 CFR 101.93**  
**Products: GUNA-NONI**

Dear Sirs,

Pursuant to 21 CFR 101.93, please be advised that Guna Inc. has begun to commercializing GUNA-NONI.

GUNA-NONI is labelled and promoted with statements provided for in section 403(r) (6) of the federal Food, Drug and Cosmetic Act.

The text of each structure-function statement for which the notification is now being given is:

1. A blend of 13 herbal extracts helps recovery from seasonal illness\*
2. GUNA-NONI is a carefully selected blend of 12 herbal extracts enhanced with Noni Juice, that work synergistically to support the immune system. Helps improve recovery from seasonal illness, provides support to the respiratory tract during the cold season and for smoking related troubles.\*

Each structure-function statement prominently bears the required boxed statement linked by an asterisk (\*) in the preceding copy: < \* These statements have not been evaluated by FDA. The product is not intended to diagnose, treat, cure or prevent diseases.>

Please find attached copy of the packaging.

Guna Inc. certifies that the information in this notice is complete and accurate and that the Company has substantiation that the foregoing statements are truthful and not misleading.

Please let me know if you have any further questions.

Sincerely,

Egon A. Landgraf  
Agent

Attachments

GUNA Inc. 4416 Glenwood Hills Dr. NE, Albuquerque, NM 87111  
Tel: 505-553-4445, email: [e.landgraf@gunainc.com](mailto:e.landgraf@gunainc.com)

#1779

2066-7175

**GUNA**  
biotherapeutics

**GUNA-NONI**  
Dietary supplement

A blend of 13 herbal  
extracts helps recovery from seasonal illness\*

150 ml / 5.07 fl. oz.

These statements have not been evaluated  
by the U.S. Food and Drug Administration.  
This product is not intended to diagnose,  
treat, cure or prevent any disease.

Other Ingredients: Water, Citric Acid, Natural  
Flavor, Vitamin C, Vitamin E, Vitamin B6,  
Vitamin B12, Zinc, Magnesium, Potassium,  
Calcium, Iron, Sodium, Potassium, Potassium,  
Potassium, Great Valley, Sunwood,  
Maiden Hair Fern, Round-leaf Sundew,  
Licorice, Curry Bush, Horehound, Royal  
Jelly, Hydroxypropyl methylcellulose,  
Stabilan (preservative).

MADE IN ITALY

**GUNA**  
biotherapeutics

GUNA INC.  
ALLIANCE  
NOV 67112  
www.gunabio.com

PET

100% NATURAL

Dietary Supplement  
**GUNA-NONI**

**GUNA**  
biotherapeutics

GUNA-NONI is a carefully selected blend of 12 herbal extracts enhanced with Noni juice that work synergistically to support the immune system. Helps improve recovery from seasonal illness, provides support to the respiratory tract during the cold season and for smoking-related troubles.

GUNA-NONI has a delicious herbal taste, the unique Noni flavor is supplemented with 12 pleasant tasting traditional herbs.

*\*These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.*

Made in Italy  
**GUNA**  
biotherapeutics

GUNA Inc.  
Albuquerque,  
NM 87112  
www.gunainc.com

**Advanced Formula  
NONI + 12 Herbs**

**Glucose  
Sucrose Free**

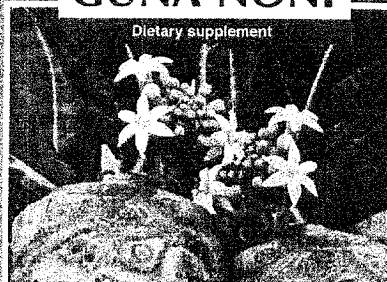


PLEASANT-TASTING  
FORMULA

**GUNA**  
biotherapeutics

**GUNA-NONI**

Dietary Supplement



**A blend of 13 herbal  
extracts helps recovery  
from seasonal illness\***

150 ml / 5.07 fl. oz.

**Supplement Facts**

Serving size 30 ml / 1.0 fl. oz.  
Servings per container 5

	Amount per serving	% Daily value
Calories	68Kcal	
Total fat	0.03	< 1
Saturated fat	0	< 1
Cholesterol	0	< 1
Total carbohydrate	16.62 g	< 1
Protein	0.35 g	< 1
Proprietary blend	15 ml	*

% Daily value is based on a 2,000 calories diet  
\* Daily value not established

**Ingredients:**

Water; Noni; Fructose syrup; Ethyl alcohol (6%); Yellow Starwort; Cowslip; Common Mallow; Corn Poppy; English Plantain; Rosemary; Great Valley Gumweed; Maiden Hair Fern; Round-leaf Sundew; Licorice; Curry Bush; Horehound; Royal Jelly; Hydroxypropyl methylcellulose; Stabian (preservative).

**Warnings:** If you are taking prescription medications, consult with your health care provider before using this product. If pregnant or breast-feeding, ask a health professional before use.

**Recommended dosage:** Adults and Children 6 years and over: 1 dosage cup 3 times a day. Children under 6 years: 1/2 adults dosage.

**Questions?:** info@gunainc.com

**Do not use if tamper-evident seal from neck of bottle is removed.**



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